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UNITED STATES OF AMERICA,	)	C.A. No. 20-1744-CFC
	)	
Plaintiff,	)	
	)	
v.	)	
WALMART INC. and	)	
WAL-MART STORES EAST, LP,	)	
	)	
Defendants.	)	
	)	
	)	

	)	
UNITED STATES OF AMERICA,	)	C.A. No. 20-1744-CFC
	)	
Plaintiff,	)	
	)	
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WAL-MART STORES EAST, LP,	)	
	)	
Defendants.	)	
	)	
	)	

Walmart’s Motion to Stay, D.I. 55 (“Motion”), argues for a complete and lengthy stay of this case, likely for well more than half a year, because the Supreme Court has granted certiorari in two criminal cases, *Ruan v. United States*, \_\_\_ S. Ct. \_\_\_, 2021 WL 5148067 (U.S. Nov. 5, 2021) (mem.), and *Kahn v. United States*, \_\_\_ S. Ct. \_\_\_, 2021 WL 5148069 (U.S. Nov. 5, 2021) (mem.). Walmart ignores the significant differences between the issues in those cases and this one. The questions presented in *Ruan* and *Kahn* have little to no actual relevance to this case at the motion-to-dismiss stage, or potentially at all. This case should proceed in its ordinary course.

## **RELEVANT FACTS AND PROCEEDINGS**

1. The United States’ civil suit against Walmart, which was filed on December 22, 2020, claims that Walmart violated the Controlled Substances Act over an extended period of time, in two roles—as a pharmacy dispensing controlled substances from June 26, 2013, through the present, and as a distributor filling controlled-substance orders from its pharmacies from June 26, 2013, through November 29, 2017. D.I. 1 ¶¶ 25, 27. The Complaint alleges that Walmart’s failure to comply with the CSA during the prescription drug abuse epidemic has resulted in significant public harm. *Id.* ¶¶ 38-44.

The Complaint seeks two forms of relief. For Walmart’s alleged dispensing violations, the United States seeks both civil penalties and injunctive relief. *Id.*

¶¶ 697-706. For Walmart’s alleged distribution violations, the Complaint seeks civil penalties. *Id.* ¶¶ 707-10.

The Complaint asserts three claims. Claims 1 and 2 address Walmart’s pharmacy conduct. Claim 1 alleges that Walmart violated 21 C.F.R. § 1306.04(a), which prohibits a “person” from “knowingly filling” invalid controlled-substance prescriptions. *Id.* ¶¶ 12-26, 697-701. Claim 2 alleges that Walmart violated 21 C.F.R. § 1306.06, which permits pharmacists to fill controlled-substance prescriptions only if they are “acting in the usual course of ... professional practice....” *Id.* ¶¶ 12-26, 702-06. Claim 3 addresses Walmart’s role as a distributor, and alleges that Walmart violated 21 C.F.R. § 1301.74(b), which required it to report suspicious controlled-substance orders that it received from its own pharmacies.

The United States’ claims are brought under the CSA’s civil penalties provisions, 21 U.S.C. §§ 842(a), (c)(1), which—unlike the CSA’s main criminal penalties provisions, *e.g.*, §§ 841, 843—do not require proof of scienter. Only Claim 1—for which the regulation permits penalties only where the conduct is done “knowingly”—requires proof of knowledge. Claims 1 and 2 are also brought under the CSA’s injunctive-relief provision, 21 U.S.C. § 843(f).

2. On February 22, 2021, Walmart moved to dismiss. D.I. 27. As to Claim 1, Walmart focused on knowledge. It argued that the Complaint does not

plausibly allege that Walmart employees knowingly filled invalid prescriptions. *Id.* at 5-17. As to Claim 2, Walmart argued that the Complaint does not plausibly allege that Walmart pharmacists, when filling prescriptions, failed to comply with the “usual course of ... professional practice” as required by § 1306.06. *Id.* at 27. Walmart further argued that even if its conduct violated § 1306.06, the CSA does not provide civil penalties for those violations. *Id.* at 19. Walmart also moved to dismiss Claim 3.<sup>1</sup>

Discovery has not commenced yet on any of the claims.

3. On November 5, 2021, the Supreme Court granted certiorari in two cases involving convictions of doctors under 21 U.S.C. § 841(a), which makes it unlawful to “knowingly or intentionally” dispense controlled substances “[e]xcept as authorized by this subchapter.” The questions presented in those petitions focus on the jury instructions a court must provide on criminal intent in such cases.

The *Ruan* petition has one question presented, which addresses the proper jury instructions for a “good faith” defense in prosecutions under § 841(a):

Whether a physician alleged to have prescribed controlled substances outside the usual course of professional practice

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<sup>1</sup> As to Claim 3, Walmart argued that the Complaint did not allege facts plausibly showing that, in its role as a distributor, it violated the reporting requirement in § 1301.74(b). It further argued that even if its conduct violated that rule, the CSA does not provide civil penalties for those violations. *Id.* at 28-32. Walmart’s motion for a stay acknowledges that the two Supreme Court cases on which the motion is predicated have no relevance to Claim 3. Mot. at 8.

may be convicted of unlawful distribution under 21 U.S.C. § 841(a)(1) without regard to whether, in good faith, he “reasonably believed” or “subjectively intended” that his prescriptions fall within that course of professional practice.

In *Kahn*, there are three questions presented. The first two similarly focus on the proper instructions to be given in § 841(a) prosecutions regarding criminal intent and the good-faith defense:

- (1) Whether, when the government prosecutes a medical practitioner under the Controlled Substances Act for issuing a prescription outside “the usual course of professional practice,” the government is required to prove that the doctor knew or intended that the prescription be outside the scope of professional practice;
- (2) whether a “good faith” defense in the context of a licensed medical practitioner prosecuted under the Controlled Substances Act protects doctors who have a honest but mistaken belief that they have issued the charged prescription in “the usual course of professional practice,” and, if so, whether that belief must be objectively reasonable;....

The third question presented in *Kahn* involves § 1306.04(a), which states, in its first sentence, “A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” In the proceedings below, the Tenth Circuit held, “§ 841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice.” *United States v. Kahn*, 989 F.3d 806, 825

(10th Cir. 2021). The Supreme Court granted certiorari on the following question:

(3) whether the “usual course of professional practice” and “legitimate medical purpose” prongs of 21 C.F.R. § 1306.04(a) must be read in the conjunctive or the disjunctive.

The questions presented in *Ruan* and *Kahn* thus focus on the instructions courts should provide on *mens rea* in prosecutions of doctors under § 841(a) and § 1306.04(a). The questions presented, as written, do not ask the Supreme Court to resolve the meaning of the “usual course of professional practice.”

## ARGUMENT

### I. Legal Standard

Whether to stay proceedings “is a matter left to the Court’s discretion.” *Amgen v. Hospira, Inc.*, No. 20-cv-0561, 2021 WL 65065, at \*1 (D. Del. Jan. 7, 2021) (Connolly, C.J.). The party seeking a stay must demonstrate “a clear case of hardship or inequity..., if there is even a fair possibility that the stay . . . will work damage to some one else.” *Landis v. N. Am. Co.*, 299 U.S. 248, 254-55 (1936). Only in “rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both.” *Id.* at 255. In determining whether to stay a case, courts often consider: “(1) whether a stay will simplify the issues and trial of the case, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or

present a clear tactical disadvantage to the non-moving party.” *Amgen*, 2021 WL 65065, at \*1.

**II. A Long Stay Is Not Warranted Given the Questions Presented in *Ruan* and *Kahn* and the Stage of Proceedings in this Case.**

**A. Walmart’s speculation that *Ruan* and *Kahn* could potentially affect Counts I and II does not support a stay.**

Walmart has failed to demonstrate that a stay will simplify the issues and trial of this case. Walmart’s Motion is premised on speculation about the possible impact of *Ruan* and *Kahn*, but such speculation does not support a stay at this stage of litigation. *Cf. Migyanko v. Dunham's Athleisure Corp.*, No. 19-514, 2021 WL 3619683, at \*1 (W.D. Pa. Aug. 16, 2021) (“speculation” that a higher court “may overturn extant precedent in an unrelated action at some point in the future on issues that may apply here is woefully insufficient to establish grounds for a stay.”). Contrary to Walmart’s suggestion, it is unlikely that the Supreme Court’s resolution of the questions presented in *Ruan* and *Kahn* would affect the resolution of Walmart’s motion to dismiss. In addition, the Supreme Court’s decisions in those cases may not have any bearing on how the government proves, or Walmart defends against, Claims 1 and 2 at trial. Moreover, as noted below, even absent a stay the parties will have sufficient time to conform their discovery and proof, if needed, to the Supreme Court’s rulings.

Walmart first claims that *Ruan* and *Kahn* will affect Claim 2. As set forth

above, *Ruan* and *Kahn* present questions about the *mens rea* requirement to prove that a prescriber committed a crime under 21 U.S.C. § 841(a) and the availability and contours of a good-faith defense to criminal liability. These questions have no relevance to Claim 2, which alleges that Walmart is liable for civil penalties under 21 U.S.C. § 842(c)(1)(A), a provision that does not impose a *mens rea* requirement.

Walmart speculates that the Court’s opinions nevertheless might “shed light on” Claim 2, as that claim involves the “usual course of professional practice” standard. Mot. at 6. But the questions presented in *Ruan* and *Kahn*, as written, appear to assume conduct outside the “usual course of professional practice” and instead address the *mens rea* and subjective beliefs doctors must have to face criminal liability for such conduct under § 841(a).<sup>2</sup>

Walmart next argues that *Ruan* and *Kahn* might affect Claim 1. Walmart contends that the Supreme Court might issue a ruling that, in prosecutions of doctors under 21 U.S.C. § 841(a), the government must prove “that a subjective good-faith belief in the legitimacy of the prescription defeats liability.” Mot. at 7. Walmart speculates that such a ruling would require the government to further prove, in a civil

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<sup>2</sup> Moreover, even if the Supreme Court were to endorse a good-faith defense in criminal actions against prescribers under § 841(a) and courts *then* were to extend a similar defense to pharmacists in civil actions for violations of § 1306.06, such a defense would not be an issue to be resolved at this motion-to-dismiss stage, which focuses on whether the Complaint states a claim. *In re Tower Air, Inc.*, 416 F.3d 229, 242 (3d Cir. 2005) (“As we have said, affirmative defenses generally will not form the basis for dismissal under Rule 12(b)(6).”).



case involving a pharmacist, two layers of knowledge—a pharmacist’s knowledge of the prescriber’s knowledge. In other words, Walmart speculates that a Supreme Court ruling on the good-faith defense in criminal prosecutions under § 841(a) could mean that the government is required to prove here that “Walmart’s pharmacists *knew* that prescribing doctors lacked a *subjective* good-faith belief in the validity of their chosen treatments.” Mot. at 7.

But even if, as Walmart speculates, the Supreme Court were to issue that ruling on the good-faith defense in criminal prosecutions under § 841(a), that ruling would not change the requirements for proving, in this civil case, that Walmart violated § 1306.04(a). Such a ruling on the criminal intent in prosecutions under § 841(a) would not require courts, in civil cases, to adopt a new pharmacist-knowledge-of-prescriber-knowledge standard for showing violations of § 1306.04(a). There is no basis for this standard in civil cases under the CSA’s strict-liability civil penalty provision, § 842(c)(1), or in § 1306.04(a). Indeed, Walmart has not argued for such a standard in its motion to dismiss.

Walmart next contends that, depending on the outcome in *Kahn*, the government might have to prove in prosecutions under § 841(a) that a prescriber issued a prescription that the prescriber knew was not for a legitimate medical purpose *and* knew was outside the usual course of professional practice. Mot. at 7. But even if the Supreme Court so rules, it is unclear that a requirement that the

government meet this burden in prosecutions of doctors under § 841(a) would change the longstanding regulatory definition in § 1306.04(a) of a valid controlled-substance prescription as it applies to this civil case. In any event, the Complaint already alleges facts plausibly showing that Walmart knowingly filled prescriptions that both lacked a legitimate medical purpose and were outside the usual course of professional practice. *See, e.g.*, D.I. 1, ¶¶ 22, 25, 107, 111.

With respect to Claim 3, which involves Walmart’s conduct as a distributor in filling controlled-substance orders from its pharmacies, Walmart concedes that the Supreme Court’s treatment of *Ruan* and *Kahn* will not affect or simplify the issues and trial of that claim. Mot. at 8. In other words, even in Walmart’s view, much of this case will not be affected by the resolution of *Ruan* and *Kahn*.

In sum, given the criminal contexts and specific questions presented in *Ruan* and *Kahn*, there is no justification for a stay of the case—especially given the lengthy stay Walmart seeks here. In reality, what Walmart characterizes as a “short” stay of more than seven months would likely be longer. The Supreme Court may not issue its opinions in these cases until June 2022, more than a year and a half after the Complaint was filed. Even when those decisions are issued, the parties may dispute their significance to the case and request briefing on the issues. The better course is to proceed with discovery and later evaluate whether the Supreme Court’s rulings have any bearing on this case.

**B. The Stage of this Litigation, and Complexity of the Case, Further Militate Against a Stay.**

Ordinarily, the early stage of a case might weigh in favor of a stay, but not so here. The Complaint was filed in December 2020. Walmart's requested stay could delay the resolution of the motion to dismiss until late summer or fall of 2022, approaching two years after the Complaint was filed.

Nor is there any risk that the case would proceed to dispositive motions or trial before the Supreme Court rules. Discovery is likely to continue well after the Supreme Court issues its ruling, as the issues in this case are complex and will require extensive discovery relating to Walmart's pharmacies and distribution centers. Should the Supreme Court issue its decision by June 2022, the parties will be just a few months into what is likely a year-plus fact-discovery schedule. If the Supreme Court's decisions in *Ruan* and *Kahn* have any effect on this litigation, the parties will have plenty of time to adjust and proceed with any necessary fact discovery accordingly.

The court in *Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, 232 F. Supp. 3d 628 (D. Del. 2017), adopted this same reasoning in denying a stay pending Supreme Court proceedings and instead delaying the trial date to after the Supreme Court's anticipated decision. *Id.* at 631. The court reasoned that the parties would still have three months to prepare for trial with the benefit of the Supreme Court's decision. *Id.* A stay here is equally unnecessary: discovery could proceed, and the

parties still would have ample time (far more than three months) to factor the Supreme Court's decisions into their discovery and any pretrial motions.

### **C. A Stay Will Cause Prejudice.**

A stay would cause prejudice by unnecessarily delaying resolution of Walmart's motion to dismiss. Most importantly, the United States seeks penalties and injunctive relief against Walmart for its failure to follow basic rules to ensure that when it dispenses opioids and other controlled substances to the public, it does so in a safe manner. The Complaint alleges that Walmart may be continuing to flout those rules and putting the public's health at risk. In light of the ongoing prescription drug abuse epidemic, it is important that the government be permitted to keep moving this case forward to resolution. *Cf. Gabelli v. SEC*, 568 U.S. 442, 451-52 (2013) ("In a civil penalty action, the Government is not only a different kind of plaintiff, it seeks a different kind of relief.... [P]enalties ... go beyond compensation...").<sup>3</sup>

In contrast, Walmart faces no unfair prejudice. Even if the Court assumes that the Supreme Court might say something of relevance to this case in resolving *Ruan*

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<sup>3</sup> If the Court grants a stay, the government may seek relief from the Court to permit it to access the documents that Walmart has produced into the repository of documents in *In Re National Prescription Opiate Litig.*, Case No. 1:17-md-02804-DAP (N.D. Ohio), pursuant to the terms of the applicable protective order in that case. Presently, other non-MDL parties who have claims against the MDL defendants, including Walmart, have access to the repository.

and *Kahn*, Walmart will have ample opportunity, after the decisions are issued, to argue about how those decisions should affect the future course of this litigation.

### **CONCLUSION**

Walmart has not shown that the lengthy stay it seeks is warranted by the questions presented in *Ruan* and *Kahn*, let alone that a stay is necessary to prevent unfair hardship. The Court should deny the request for a stay.

MICHAEL D. GRANSTON  
Deputy Assistant Attorney  
General for  
the Civil Division

GUSTAV W. EYLER  
Director  
ADAM E. LYONS  
Assistant Director  
JOSHUA FOWKES  
KATHLEEN B. GILCHRIST  
AMY KAPLAN  
BRANDON ROBERS  
Trial Attorneys  
U.S. Department of Justice  
Civil Division  
Consumer Protection Branch  
P.O. Box 386  
Washington, DC 20044  
gustav.w.eyler@usdoj.gov  
202-307-0066

MATTHEW T. KIRSCH  
Acting United States Attorney  
for the District of Colorado

/s/ Kevin T. Traskos  
KEVIN T. TRASKOS  
AMANDA A. ROCQUE  
JASAND P. MOCK  
Special Attorneys to the Attorney General  
1801 California Street, Suite 1600  
Denver, CO 80202  
kevin.traskos@usdoj.gov  
303-454-0100

KARIN HOPPMANN  
Acting United States Attorney  
for the Middle District of Florida

KATHERINE M. HO  
LACY R. HARWELL, JR.  
LINDSAY S. GRIFFIN  
CAROLYN B. TAPIE  
Special Attorneys to the Attorney General  
400 West Washington Street, Suite 3100  
Orlando, FL 32801  
katherine.ho@usdoj.gov 407-648-7500

DAVID C. WEISS  
United States Attorney for the  
District of Delaware

/s/ Laura D. Hatcher  
LAURA D. HATCHER  
DYLAN STEINBERG  
1313 N. Market Street  
Wilmington, DE 19801  
laura.hatcher@usdoj.gov  
302-573-6277

MARK J. LESKO  
Acting United States Attorney  
for the Eastern District of New York

ELLIOT M. SCHACHNER  
JAMES KNAPP  
JOLIE APICELLA  
MEGAN FREISMUTH  
Special Attorneys to the Attorney General  
271 Cadman Plaza East  
Brooklyn, NY 11201  
elliot.schachner@usdoj.gov  
718-254-7000

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